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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/615,872	07/13/2000	Gowthami M. Arepally	2687-021/MC-166	4363

22208 7590 09/14/2004

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EXAMINER

GRUN, JAMES LESLIE

ART UNIT PAPER NUMBER

1641

DATE MAILED: 09/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/615,872	AREPALLY ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	James L Grun	1641	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 August 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-3,5,6,12-14 and 42-46 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3,5,6,12-14 and 42-46 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

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To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Technology Center 1600, Group 1640, Art Unit 1641.

The amendment filed 27 August 2004 is acknowledged and has been entered. Claims 42-46 are newly added. Claims 4, 7-11, and 15-41 have been cancelled. Claims 1-3, 5, 6, 12-14, and 42-46 remain in the case.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The disclosure is objected to because of the following informalities: the imbedded active hyperlinks on page 23 are an impermissible incorporation by reference of the information on the referenced web page and require deletion of elements which make them active, including deletion of "http://", and underlining. Appropriate correction is required.

Claims 1-3, 5, 6, 12-14, and 42-46 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons of record in the prior rejection of claims 1-3, 5, 6, and 12-14 wherein a deposit requirement was made and applicants were deemed not to be in compliance with the Deposit rules. The copy of the receipt form sent by the ATCC is sufficient to show that viable cells were deposited under the terms of the Budapest Treaty. However, applicants have not provided the proper corroboration that the deposited cell line is the biological material specifically identified in the application (see MPEP § 2406.02). Applicant is also reminded that information regarding the deposit, such as the accession number of the deposit and the date(s) of the deposit, in addition

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to the name and address of the depository, **must** be added to the specification by means of filing an amendment as required by 37 CFR § 1.809(d). In the instant case, the insert to page 56 directed in the amendment filed 22 July 2002 should be amended.

Applicant's arguments filed 27 August 2004 have been fully considered but they are not deemed to be persuasive. Applicant urges that the deposit of the KKO cell line as ATCC PTA-6133 is in compliance with 37 CFR §§ 1.801-1.809 and thus shows possession of and enables the invention as instantly claimed. This is not found persuasive in view of the deficiencies noted above.

The specification is objected to and claims 12-14 and 44-46 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons of record that the claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, and which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, particularly the invention commensurate in scope with these claims.

Applicant's arguments filed 27 August 2004 have been fully considered but they are not deemed to be persuasive. Applicant urges that the deposit of the KKO cell line as ATCC PTA-6133 is in compliance with 37 CFR §§ 1.801-1.809, that competitive assays with polyclonal antibody subsets found in patient samples are exemplified, and that these thus show possession of, and sufficient enabling disclosure for, the invention as instantly claimed. This is not found persuasive for the reasons of record that one would not know or be able to predict or envision

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what structure or modifications were important for function, particularly because one would not even know which of the two light chain sequences of the “single” disclosed antibody species was functional in the invention. As set forth, given the instant guidance and absent further unguided experimentation, one would not know or be able to predict or envision what variable region changes would predictably function in the invention other than those possessing both the intact  $V_H$  and  $V_L$ - chains of the KKO antibody. Random experimentation within the huge genus embraced by applicant's claims with no predictability that a given antibody would function or not function in the invention is undue experimentation. Absent knowledge of relevant structures, other than that of the intact KKO antibody, one would not be able to predict the structure of, or make or use, any humanized antibody that did not comprise all of the complementarity determining regions of the KKO antibody. Again, an enabling disclosure for the preparation and use of only a few analogs of a product does not enable all possible analogs where the characteristics of the analogs are unpredictable.

Claim 6 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant's specification provides no written description for the production of a humanized antibody by a deposited murine hybridoma designated ATCC PTA-6133.

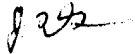
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to James L. Grun, Ph.D., whose telephone number is (571) 272-0821. The examiner can normally be reached on weekdays from 9 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, SPE, can be contacted at (571) 272-0823.

The phone numbers for official facsimile transmitted communications to TC 1600, Group 1640, are (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application, or requests to supply missing elements from Office communications, should be directed to the Group receptionist whose telephone number is (571) 272-1600.



James L. Grun, Ph.D.  
September 10, 2004



CHRISTOPHER L. CHIN  
PRIMARY EXAMINER  
GROUP 1800/641  
9/10/04